



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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Thomas A. Swinford, Ph.D.
Mead Johnson Nutritionals
2400 West Lloyd Expressway
Evansville, Indiana 47721

Re: Docket: 00P-0425/CP1

Dear Dr. Swinford:

This letter refers to your citizen petition, Docket Number 00P-0425/CP1, which was filed with the Food and Drug Administration (FDA) on February 3, 2000. Your petition requests replacement of 21 CFR 107.10(b)(4)(i) and (ii) with the following wording:

(4) If the formula contains less than 1 milligram of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption, a statement such as "Low Iron" shall appear on the principal display panel and a statement such as "Additional Iron May Be Necessary" shall appear on the information panel.

In accordance with 21 CFR 10.30(e)(2), this letter is to advise you that we have been unable to reach a decision on your petition within the first 180 days of its receipt because of other Agency priorities and the limited availability of resources. However, as you are aware, the Agency intends to revise nutrient requirements for infant formulas (21 CFR 107.100). We also plan to propose labeling changes to be consistent with any revisions in nutrient requirements, and intend consideration of this citizen petition to be part of that endeavor.

Sincerely yours,

Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

00P-0425

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